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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/023,634 | 12/17/2001 | Kimberly A. Spytek | 21402-221 (Cura 521) | 4413 |

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| EXAMINER | |
|---|---|
| STEADMAN, DAVID J | |
| ART UNIT | PAPER NUMBER |
| 1652 | |

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/023,634 | SHIMKETS ET AL. | |
| | Examiner | Art Unit | |
| | David J Steadman | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *42-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/02/03; 04/19/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Application*

**[1]** Claims 42-51 are pending in the application.

**[2]** Applicants' amendment to the claims, filed November 22, 2003, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

**[3]** Receipt of a petition to correct inventorship under 37 CFR 1.48(b), filed November 22, 2003, is acknowledged. It is noted that applicants need only file a request and not a petition to change inventorship under 37 CFR 1.48(b) (see item [22] of the Office action mailed September 23, 2003).

**[4]** Receipt of an information disclosure statement (IDS), filed October 22, 2003, is acknowledged.

### *Election/Restriction*

**[5]** Applicants' election with traverse of the invention of Group II and Group vv, filed November 22, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### *Information Disclosure Statement*

**[6]** All references cited in the IDSs filed April 02, 2003 and April 19, 2002 have been considered by the examiner and a copy of each IDS is attached to the instant Office action.

**[7]** The information disclosure statement filed October 22, 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the cited U.S. patent application publications are not identified by applicant and publication date as required by 37 CFR 1.98 (b)(2). It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

***Correction of Inventorship***

**[8]** In view of the papers filed November 22, 2003, the inventorship in this nonprovisional application has been changed by the deletion of Richard Shimkets, Steven Colman, Robert Ballinger, Maojia Guo, Velizar Tehernev, Li Li, Karen Ellerman, Bryan Zerhusen, Meera Patturajan, Stacie Casman, Ferenc Boldog, Vladimir Gusev, Catherine Burgess, Shlomit Edinger, Esha Gangolli, Uriel Malyankar, Erik Gunther, Glennda Smithson, Isabelle Millet and Valerie Gerlach.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

***Specification/Informalities***

**[9]** The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "Polynucleotide Encoding A Human Epidermal Growth Factor-Like Protein".

**[10]** The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification at page 11, line 20 and page 14, line 6 (and all other instances in the specification), is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

**[11]** The use of the trademarks "Triton®", "Thesit®", and "TaqMan®" has been noted in this application (see pages 140 and 164). The trademarks cited above and all others used in the specification should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC §§ 101 and 112, First Paragraph***

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**[12]** Claims 42-51 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to an isolated nucleic acid molecule encoding SEQ ID NO:12 (referred to in the specification as NOV5 – see, e.g., pages 37-44), including SEQ ID NO:11, a complement thereof, a vector, a cell, a pharmaceutical composition, and a kit. Based on characteristics of the sequence of SEQ ID NO:12, the specification asserts that NOV5 "may function as a member of a Epidermal Growth Factor-like protein family (page 43, bottom) and that "NOV5 nucleic acids and proteins of the invention are useful in potential therapeutic applications implicated in various diseases and disorders described below and/or other pathologies. For example, the NOV5 compositions of the present invention will have efficacy for treatment of patients suffering from Agammaglobulinemia, type 2, X-linked; Aicardi syndrome; Craniofrontonasal dysplasia; Deafness, X-linked 6, sensorineural; Goiter, multinodular, 2; Mental retardation, X-linked nonspecific, 58; Opitz G syndrome, type 1; Partington syndrome II; Simpson-Golabi-Belzmel syndrome, type 2; Simpson-Gblabi-Behmel syndrome, type 2; Oncogenesis; fertility; regulation of cell cycle, proliferation and developmental processes. The NOV5 nucleic acid encoding these Epidermal Growth

Factor-like protein, and the Epidermal Growth Factor-like protein of the invention, or fragments thereof, may further be useful in diagnostic applications, wherein the presence or amount of the nucleic acid or the protein are to be assessed" (page 44, top).

The claims are rejected because the asserted utilities are neither specific nor substantial as described in detail below. MPEP 2107.01 defines a "specific utility" as a utility that "is specific to the subject matter claimed", which "contrasts with a general utility that would be applicable to the broad class of the invention". In the instant case, use of the claimed nucleic acid for assessing the presence or amount of the nucleic acid is not specific as any nucleic acid can be used for such a utility.

Also, MPEP 2107.01 defines a "substantial utility" as a utility that "defines a 'real world' use" and that "[u]tilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities." In the instant case, use of the claimed nucleic acid for disease treatment or diagnosis is not substantial. The use of the claimed nucleic acid for therapeutic and diagnostic applications, it is noted that there is no evidence of record that would suggest that the claimed nucleic acid or the encoded polypeptide is associated with any disease state. Only by further research would a skilled artisan be able to determine whether the claimed nucleic acid is useful for treating or diagnosing a disease state and thus, the claimed nucleic acid fails to provide an immediate benefit to the public in currently available form. It is noted that MPEP 2107.01, describing utilities that are not substantial, states, "[a] method of assaying for or identifying a material that itself has no

specific and/or substantial utility." Thus, the use of the claimed nucleic acid as a diagnostic by assessing the presence or level of the nucleic acid is not substantial. The specification must teach a skilled artisan how to use what is claimed and not merely provide a blueprint for further experimentation in order for an artisan to identify a use for the claimed invention. See Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). As stated in Brenner v. Manson, 383 U.S. 519 535-536, 148 USPQ 689, 696 (1966), "[a] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion".

It should be noted that the specification fails to assert a function for the polypeptide encoded by SEQ ID NO:11. While the specification asserts that SEQ ID NO:12 is an Epidermal Growth Factor-like protein, the examiner has not interpreted this as an assertion of function – only that that SEQ ID NO:12 is "like" the sequence (not function) of an Epidermal Growth Factor protein. As there is no evidence that SEQ ID NO:12 has the function of an Epidermal Growth Factor protein, it is just as likely that SEQ ID NO:12 has some other function or is a non-functional variant of an Epidermal Growth Factor protein. The specification provides evidence suggesting that the amino acid sequence of SEQ ID NO:12 is most related to the amino acid sequence of mouse nephronectin (see Table 5E at page 39). However, even if SEQ ID NO:12 is a human ortholog of mouse nephronectin, further experimentation would be required to identify a "real-world" use for the claimed nucleic acid, particularly in view of the teachings of Brandenberger et al. (J Cell Biol 154:447-458; cited by applicants in the IDS filed April

19, 2002), who suggest that nephronectin is useful only for further research (see page 456).

**[13]** Claims 42-51 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**[14]** Claim(s) 46 and 48-50 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**[a]** Claims 46 and 50 recite the limitations "said nucleic acid molecule" and "the nucleic acid molecule". There is insufficient antecedent basis for these limitations in the claims. It is suggested that applicants amend the terms to, for example, "said nucleic acid sequence" or "the nucleic acid sequence."

**[b]** Claim 48 is indefinite in the recitation of "mature form of the polypeptide of SEQ ID NO:12". The specification defines the term "mature" as "the product of a naturally occurring polypeptide or precursor form or proprotein" (pages 92-93 of the specification). However, it is unclear from this "definition" as to the scope of

polypeptides that are considered to be mature or immature forms of SEQ ID NO:12. It is suggested that applicants clarify the meaning of the term "mature form".

**[c]** Claim 49 is confusing in the recitation of "nucleic acid sequence encoding the complement". Nucleic acids encode polypeptides, not other nucleic acids or complements thereof. Furthermore, it is noted that it is unclear from the specification as to whether the "complement of a polynucleotide of SEQ ID NO:11" is a full or partial complement of SEQ ID NO:11 and thus, it is unclear as to the scope of claimed polynucleotides. For purposes of examination, the examiner has interpreted the term as meaning a full complement of SEQ ID NO:11. It is suggested that applicants clarify the meaning of the claim.

### *Claim Rejections – Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**[15]** Claim 48 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 23 of US non-

provisional application 10/453,372 ('372 Application). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application are drawn to an isolated polynucleotide comprising a nucleic acid sequence encoding the mature form of the polypeptide of SEQ ID NO:12. Claim 23 of the '372 Application is drawn to a an isolated nucleic acid molecule encoding the mature form of a polypeptide having an amino acid sequence selected from the group consisting of SEQ ID NO:2n, wherein n is an integer between 1 and 606. It should be noted that SEQ ID NO:12 of the instant application is encompassed by the polypeptide sequences of SEQ ID NO:6, 22, 24, 28, and 30 of the '372 Application and that SEQ ID NO:12 of the instant application is encoded by the nucleic acids of SEQ ID NO:5, 21, 23, 27, and 29 of the '372 Application. The claims differ in that claim 48 of the instant application is limited to a nucleic acid encoding SEQ ID NO:12. The portion of the specification of the '372 Application that supports the claimed nucleic acid includes an embodiment of claim 23, i.e., an isolated nucleic acid encoding the mature form of SEQ ID NO:6, 22, 24, 28, and 30 of the '372 Application. Claim 48 of the instant application cannot be considered to be patentably distinct over claim 23 of the '372 Application

when there is a specifically recited embodiment in the '372 Application that would anticipate claim 48. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

**[16]** Status of the claims:

- Claims 42-51 are pending.
- Claims 42-51 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

04-28-04